

ROUTING AND TRANSMITTAL SLIP

Date

11/04/19

TO: (Name, office symbol, room number,
building, Agency/Post)

Initials

Date

1. Rachel Matney/Anna Hassan, IOAA

AMH

11/6/19

2. Tia Groves/Robin Clarke, IOAA

TG

11/6/19

3. Elizabeth Blackburn, Chief of Staff (CoS)/Dale Perry, Deputy, CoS, IOAA

EB

11/6/17

4. Jennifer Orme-Zavaleta, Principal Deputy Assistant Admin. for Science

JOZ

11/6/17

5.

Jennifer

6.

7.

8.

9.

10.

<input type="checkbox"/> Action	<input type="checkbox"/> File	<input type="checkbox"/> Note and Return
<input checked="" type="checkbox"/> Approval	<input type="checkbox"/> For Clearance	<input type="checkbox"/> Per Conversation
<input type="checkbox"/> As Requested	<input type="checkbox"/> For Correction	<input type="checkbox"/> Prepare Reply
<input type="checkbox"/> Circulate	<input type="checkbox"/> For Your Information	<input type="checkbox"/> See Me
<input type="checkbox"/> Comment	<input type="checkbox"/> Investigate	<input checked="" type="checkbox"/> Signature
<input type="checkbox"/> Coordination	<input type="checkbox"/> Justify	

REMARKS

5170 REVIEW & SIGNATURE NEEDED

2019 - ORD - COTE- 5170 - First Annual Conference on New Approach Methods (NAMS): Alternatives to Animal Testing, December 17, 2019, EPA HQs, Washington, DC.

Total estimated cost = \$69,000

- Travel for 9 EPA attendees, estimate \$9,000
- Travel for 4 EPA Non-EPA attendees/speakers, estimate \$6,000
- Conference support contract, estimate \$50,000
- Conference refreshments, estimate \$4,000

POC: Monica Linnenbrink, 919.541.1522

DO NOT use this form as a RECORD of approvals, concurrences, disposals,
clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)

Lisa Tychsen /s/ ORD/ORM/PBD/IO

Room No. - Bldg.

41180

Phone No.

(202) 564-2502

OPTIONAL FORM 41 (Rev. 1-94)

Prescribed by GSA



United States

ENVIRONMENTAL PROTECTION AGENCY

Washington, DC 20460

Conference-Related Activities Spending Request

AA'ship: **ORD (in coordination with OCSP)**Office: **CCTE**Contact: **Monica Linnenbrink**Phone Number: **919.541.1522**

Conference Details

Name of Event: **First Annual Conference on New Approach Methods (NAMS): Alternatives to Animal Testing**Location: **EPA HQS Washington, DC**Date & Time: **December 17, 2019**Number of Attendees: **100 est** Federal: **90 est**Non-Federal: **10 est**

Purpose:

First Annual Conference on New Approach Methods (NAMS): Alternatives to Animal Testing
--The goals of the conference are to learn about advances in the NAMS field; to provide a common understanding of the state of the science in the development of NAMS; to explore approaches to developing scientific confidence; and to set expectations in the performance of NAMS relative to existing animal models. This is a event supported and attended by EPA's Administrator.

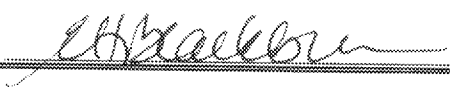
Expenses:	Quantity	Unit Cost	Price
Facility			
Audio Visual Equipment			
Room Setup Costs			
Travel (Provide cost for all EPA attendees including lodging, trans., per diem, etc)	9		\$ 9,000.00
EPA Funded Travel for Non-EPA Attendees	4		\$ 6,000.00
Conference Planning Contracts	1*		\$ 50,000.00
Facilitation and Note Taking Contracts			
Promotional or Commemorative Items (Provide an attachment with details)			
Supplies and Materials			
Other (Provide an attachment with Details) Conference refreshments			\$ 4,000.00
* Contract will provide conference logistical support, travel support for invited speakers, and a summary report.			
Total			\$ 69,000.00

Questions (to be filled out by employee providing recommendation to AA/RA)

Is EPA space or other government space available? (circle answer) ☒ Yes ☐ No
Is all of the spending necessary and reasonable? ☒ Yes ☐ No
Do all aspects of the event positively represent EPA to the public? ☒ Yes ☐ No
Does this event advance or support EPA's mission? ☒ Yes ☐ No

Recommendor (Print Name): **Elizabeth Blackburn, Chief of Staff, ORD**

Date: _____


Recommendor Approval: Date: **11/6/19**

Assistant Administrator or Regional Administrator Approval

I hereby certify that:

1. All spending for this event is appropriate and in support of program goals; and
2. All spending is necessary and reasonable.

Assistant Administrator or Regional Administrator(Print Name): Jennifer Orme-Zavaleta

Assistant Administrator or Regional Administrator Approval: 

Date: 11/6/19

If request is above \$100,000, Deputy Administrator must approve.

Deputy Administrator Approval: _____

Date: _____

This form must be submitted with your procurement package for space rental. This form must be maintained as part of the official contract, order, or purchase card file. A copy of this signed form must be sent to conference@epa.gov for periodic analysis, reporting and routing for Deputy Administrator Approval if the request is over \$100,000.

(Please note: a 5170 conference request with contract support--needs to include a copy of the TD, WA or draft SOW).

First Annual Conference on New Approach Methods (NAMS): Alternatives to Animal Testing

EPA-HQs Washington, DC- December 17, 2019

EPA Funded Travel for EPA Attendees

#	EPA Employees	Role at the Event	Laboratory, Center, or Office	Duty Station	Event Location	TOTAL
1	TBD EPA staff	Participant	CEMM	RTP, NC	Washington, DC	\$ 1,000.00
2	TBD EPA staff	Participant	CEMM	RTP, NC	Washington, DC	\$ 1,000.00
3	TBD EPA staff	Participant	CEMM	RTP, NC	Washington, DC	\$ 1,000.00
4	TBD EPA staff	Participant	CEMM	RTP, NC	Washington, DC	\$ 1,000.00
5	TBD EPA staff	Participant	CEMM	RTP, NC	Washington, DC	\$ 1,000.00
6	TBD EPA staff	Participant	CEMM	RTP, NC	Washington, DC	\$ 1,000.00
7	TBD EPA staff	Participant	CEMM	RTP, NC	Washington, DC	\$ 1,000.00
8	TBD EPA staff	Participant	CEMM	RTP, NC	Washington, DC	\$ 1,000.00
9	TBD EPA Regional Science Liason	Participant	CEMM	Chicago, IL	Washington, DC	\$ 1,000.00

Document Total Cost Estimate of EPA Employee Travel on EPA Form 5170: \$ 9,000.00

EPA Funded Travel for Non-EPA Attendees

#	Non-EPA Attendee	Role at the Event	Organization	Traveling From	Event Location	TOTAL
1	David Dorman	Speaker	NC State University, NC	Raleigh, NC	Washington, DC	\$ 1,300.00
2	Ivan Rusyn	Speaker	Texas A&M University	Corpus Christie, TX	Washington, DC	\$ 1,500.00
3	Dan Krewski	Speaker	University of Ottawa, CA	Ottawa, CA	Washington, DC	\$ 1,700.00
4	Kim Boekelheide	Speaker	Brown University, RI	Providence, RI	Washington, DC	\$ 1,500.00

Document Total Cost Estimate of Non-EPA Attendee Travel on EPA Form 5170s: \$ 6,000.00

Facility, Audio/Visual, Room Set-up, Conference Planning Contracts, Facilitation/Note Taking Contracts, and Supply and Material Costs

#	Vendor Name	Type of Supplies/Services	Vendor Location	Procurement Mechanism	Event Location	
1		Conference support		PWS	Washington, DC	\$ 50,000.00
2		Refreshments		PR	Washington, DC	\$ 4,000.00

Document Total Cost Estimate of Each Category on EPA Form 5170: \$ 54,000.00

Promotional and/or Commemorative Items

If Applicable, explain what the promotional and/or commemorative items are, estimated cost per unit, and a justification as to why the expense will be beneficial to the organization

Document Total Cost Estimate of Promotional and/or Commemorative Items on EPA Form 5170:

Other Items/Services

(e.g., inter-agency agreements, refreshments, sponsorships, honorarium, etc.)

INSTRUCTIONS: If Applicable, explain what the other expenses (products/services) are and list the ~~estimated cost per unit~~. Items involving refreshments or sponsorship need to include a justification statement.

Document Total Cost Estimate of all other items on EPA Form 5170:

TOTAL AMOUNT THAT SHOULD BE NOTATED AS THE TOTAL COST OF THE EVENT ON THE EPA FORM 5170: \$ 69,000.00

STATE OF THE SCIENCE ON DEVELOPMENT AND USE OF NAMs FOR CHEMICAL SAFETY TESTING

Location: EPA Map Room
Date: December 17, 2019
Time: 9:30 am – 5:30 pm

Agenda

8:30 am – 9:30 am	Registration	
9:30 am – 9:45 am	Welcome	Alex Dunn (EPA)
9:45 am – 10:00 am	Charge to the Group	Andrew Wheeler (EPA)

Establishing Baselines for Animal Use at EPA and Opportunities for Reduction

10:00 am – 10:20 am	Retrospective analysis of the statutory requirements, study requests, and research utilization in OCSPP and ORD	TBD, OCSPP (EPA)
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Establishing Expectations on Variability and Relevance of Current Animal Tests

10:20 am – 10:40 am	Concordance of the toxicity of pharmaceuticals in animals and human	Thomas Monticello (Amgen) or Doug Keller (Sanofi-Aventis)
10:40 am – 11:00 am	Variability of animal studies for acute toxicity, skin sensitization, and mechanistic responses	Nicole Kleinstreuer (NICEATM)
11:00 am – 11:20 pm	Qualitative and quantitative variability of repeat dose animal toxicity studies	TBD, ORD (EPA)

Lunch Break

11:20 pm – 12:20 pm	Lunch	
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State of the Science in Development and Application of Alternatives

12:20 pm – 12:40 pm	Application of NAMs for quantitative screening level risk decisions	Tara Barton-McLaren (Health Canada)
12:40 pm – 1:00 pm	Development and application of <i>in vitro</i> methods for evaluating respiratory irritants	TBD (EPA)

1:00 pm – 1:20 pm	State of the science for predicting developmental toxicity using NAMs	George Daston (P&G)
1:20 pm – 1:40 pm	Advances in the development of organotypic and tissue chip technologies for toxicity testing	Danilo Tagle (NIH)
1:40 pm – 2:00 pm	Alternative approaches for toxicokinetics	TBD, ORD (EPA)
2:00 pm – 2:20 pm	Identifying endocrine disrupting chemicals using <i>in vitro</i> and computational approaches	TBD, ORD (EPA)

Developing Scientific Confidence in NAMs

2:20 pm – 2:40 pm	New Approaches to Validation and Characterizing Performance of NAMs	Warren Casey (NICEATM)
2:40 pm – 3:00 pm	Break	

Breakout Discussions

3:00 pm – 4:30 pm	Breakout Group #1 - Expectations on Variability and Relevance of Current Animal Tests	David Dorman (NCSU) Dan Krewski (UO)
3:00 pm – 4:30 pm	Breakout Group #2 - State of the Science in Development and Application of Alternatives	Mel Andersen (Scitovation) Ivan Rusyn (TAMU)
3:00 pm – 4:30 pm	Breakout Group #3 – Developing Scientific Confidence in NAMs	Patience Browne (OECD) Kim Boekelheide (BU)
4:30 pm – 5:00 pm	Report Out	Rapporteurs
5:00 pm – 5:30 pm	Closing remarks	Jennifer Orme-Zavaleta (EPA)

Additional information

Add additional instructions or comments here.

PERFORMANCE WORK STATEMENT
CONTRACT NO. 68HERC19D0003
TO- (TO-00)**

TITLE: Support to the 2019 US EPA First Annual Conference on New Approach Methods: Alternatives to Animal Testing

Specify Section & Paragraph SOW: E2, Risk Assessment Support; Administration and Technical Support for Meetings

PERIOD OF PERFORMANCE: *CO award to Six months*

I. PURPOSE

The purpose of this task order is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) for administrative and technical support to the **2019 US EPA First Annual Conference on New Approach Methods (NAM): Alternatives to Animal Testing**, to be hosted at an EPA facility in Washington, DC the week of December 16, 2019. Conference attendance is expected to be about 150 attendees.

The desired goals of the invitation-only conference are the following:

- Learn about advances in the NAMs field
- Provide a common understanding of the state of the science in the development of NAMs
- Explore approaches to developing scientific confidence
- Set expectations in the performance of NAMs relative to existing animal models

The task order has two major components: (1) the preparation for the two-day conference to take place in EPA space in Washington, DC; and (2) on-site technical support during the 2-day conference.

II. BACKGROUND

Over the past several years, the Agency has made significant efforts to reduce, replace, and refine its animal testing requirements, and will continue to lead the way among the federal agencies. EPA OCSPP and ORD have been tasked to identify additional opportunities to take accountable steps to significantly reduce (and eventually eliminate) the number of mammals used in testing to meet the 2025 and 2035 goals set forth in the EPA Administrator September 10, 2019 memorandum. In addition, the advent of new approach methods (NAMs) for generating safety information on chemicals provides an opportune time to take stock of what chemical risk assessments could look like in the 21st century. To modernize risk assessment, there is a need to demonstrate how the data and tools can be incorporated into future risk assessments, in particular for chemicals with limited information. These advances come as the modernization of the Toxic Substances Control Act, the review of the European chemicals management law, the next phase of the Canadian Chemical Management Plan, and many international chemical management policies and laws, have escalated the need to enable sharing of data and knowledge across this regulatory landscape.

The **2019 US EPA First Annual Conference on New Approach Methods: Alternatives to Animal Testing** will be by invitation only with a cross-sectional mix of stakeholders and scientific experts. The purpose of this two-day conference is to engage a cross-sectional mix of EPA stakeholders and scientific experts in a dialogue about using new approach methods to evaluate chemicals for potential health effects. The first day of the conference will include a group of invited stakeholders and appropriate EPA staff. The conference will consist of presentations by scientific experts from outside and inside the Agency – with the vast majority being from outside – to inform attendees and the general public on advances in the NAMs field. Speakers will present on the state of the science in NAMs related to the development of new models, overcoming technical and social barriers, and advances in data analysis and computational modeling to better extrapolate effects on human health.

The second day of the conference will be for EPA personnel only to compile the information gathered during the first day and discuss next steps. The EPA workgroup is preparing a draft agenda for the conference as well as a list of invitees and potential speakers and will share these documents with the contractor when they are ready. The workgroup is planning on having a closed-door workshop for EPA personnel the day after the conference to compile information and discuss how to align Agency efforts on alternative testing and implement the US EPA Administrator's September 10, 2019 memorandum.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of award of this TO, the Contractor shall schedule a conference call (not to exceed 1 hour) with the TO-COR, ALT TO-COR, and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan in response to the Contracting Officer's RFP describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the RFP, which shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in administrative and technical support to a conference.

Task 3: PRE-CONFERENCE PREPARATION

Task 3.1. Securing Hotel Block of Rooms:

The contractor shall find and reserve a hotel near the EPA Washington DC location during the week of December 16. The Contractor shall secure a block of rooms at the hotel at the government rate for participants traveling to the conference. Preference should be given to a hotel within walking distance of the Washington DC location or close to a metro station. The Contractor shall work closely with the EPA TO-COR in selecting the conference hotel(s).

Task 3.2. Pre-registering Conference Participants:

The Contractor shall work with the necessary EPA web and IT personnel in developing an EPA based (mobile-friendly) conference registration website. At the very least, the website shall include a pre-registration page that contains information on hotel block of reserved rooms, and other pertinent logistical information. Upon receipt of a registration request, the Contractor shall ensure the person

requesting registration is on the list of invitees as provided by the EPA TO-COR. If not, the Contractor shall contact the TO-COR on whether to accept or decline the registration. The Contractor shall confirm a successful registration with the registrant or let the registrant know if the registration cannot be accepted.

The Contractor shall provide a list of pre-registrants, by way of a spreadsheet or other digital means, 4 weeks prior to the conference, and again beginning each week thereafter until the start of the conference, unless there were no new pre-registrants added during that period.

Task 4: CONFERENCE SUPPORT

Task 4.1 On-site Technical Support during Conference (e.g. Coordination with speakers, securing on-site Audio/Visual, IT support:

- The contractor shall attend the conference in-person, provide administrative and technical support for the duration.
- The contractor shall, when given a list of potential speakers, moderators, key audience members and other audience categories, obtain their appropriate power point presentations and organize these presentations in an appropriate manner to be ready to load onto EPA computers at the conference. The contractor will confirm moderator participation in cooperation with the TO-COR.
- The contractor shall coordinate with EPA facility lead to ensure that all equipment needed at the meeting is available, to include microphone equipment, laptop computers, etc., as needed and specified by the EPA TOCOR.
- The contractor shall staff a registration table each day of the meeting and shall provide table tents and name badges of participants. The contractor shall also photocopy additional sets of handouts and materials as may be required during the course of the conference, on a fast turnaround basis, as requested by the EPA TOCOR.
- The contractor will facilitate conference presentations, record discussions, action items, and decisions.
- The contractor shall set up and manage the webinar and troubleshoot any issues related to the webinar during the conference. The contractor shall also monitor webinar activity and questions for the duration of the meeting.
- The contractor shall deliver to the EPA TOCOR any materials not distributed at the meeting or materials left behind by participants within two working days after the meeting.

Task 5: CONFERENCE REPORT

- The contractor should summarize conference proceedings and distill discussion items as well as next steps.
- The contractor should summarize the proceedings for both days of the conference and provide the report to EPA following the conference.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software e.g., MS Office 2013 (or later) spreadsheets and documents.

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Task order
Task 2. Work, Staffing Plan	20 days after award
Task 3. Secure Hotel for lodging List of Registrants	20 days after award 4 weeks prior to conference and weekly up to conference date
Task 4. 1 st draft of Notes of proceedings Final version of Notes	7 days after end of conference 5 days after TOCOR approval of draft

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this task order before being approved as final.
2. The contractor shall comply with other applicable requirements for final task order reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or task order, the contractor shall immediately contact the PO, TO-COR or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA TO-COR at the initiation of the task order, and shall provide a bi-weekly update to the TO-COR by telephone for the duration of the task order, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this task order shall be sent to the PO.

Task order Manager (TO-COR):

Monica Linnenbrink
U.S. EPA, ORD/CCTE
Research Triangle Park
Durham NC
919-541-1522

Alternate TO-COR:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 31 2019

OFFICE OF
RESEARCH AND DEVELOPMENT

MEMORANDUM

SUBJECT: Request for Approval for Light Refreshments at the EPA New Approach Methods (NAMS) Conference, December 17, 2019 at EPA Headquarters, Washington, D.C.

FROM: Elizabeth Blackburn
Chief of Staff

TO: Christopher S. Robbins
Deputy Assistant Administrator for Management
Office of Research and Development

This memo is to request the authorization to purchase light refreshments for the EPA New Approach Methods (NAMS) Conference, which is all day on December 17, 2019, at EPA Headquarters, Washington, DC. Providing light refreshment items will allow more time for discussions and engagement with the meeting attendees to occur.

The conference is focused on discussions related to reducing the use of animals to test chemicals by using new approach methods. The Administrator is scheduled to speak at this conference, and ORD and OCSPP leadership, are supporting this event. This conference is the first step towards achieving the Administrator's goal of eliminating animal testing at EPA by 2035.

EPA Order 1900.3 (attached) "Food at EPA Conference, Workshop, Ceremony, Reception or Observance" specifically states in pertinent part:

1. **PURPOSE:** This Order establishes policy for: (1) determining circumstances where light refreshments, meals and/or ethnic food samples may be purchased by EPA with appropriated funds; (2) approval procedures for determinations on whether or not light refreshments, meals and/or ethnic food samples are allowable; and (3) other considerations when purchasing food.
 - a. Formal Conference authority is derived from section 103 of the Clean Air Act, Section 104 of the Clean Water Act, section 8001 of the Solid Waste Disposal Act, section 102(2) (F) and (G) of the National Environmental Policy Act, sections 104(k) (6) and 311 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).

the Government Employees Training Act (GETA), and similar statutes which allow EPA to conduct formal conferences that provide the public and other Federal agencies useful information on various aspects of environmental protection. Authority for attendance of non-Federal personnel at EPA formal conferences derives its authority from various environmental statutes which include the Clean Air Act, the Clean Water Act, the Solid Waste Disposal Act, the Comprehensive Environmental Response, Compensation, and Liability Act, and the general authority under the Intergovernmental Cooperation Act to admit state, tribal, and local government employees to EPA conferences.

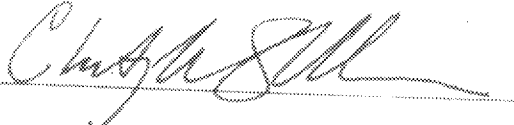
In addition, the Order also states:

b. An approving Official designated in EPA Delegation 1-51 must provide documentation which:

According to EPA Delegation 1-51, the authority for approving such refreshments must be delegated to the Office Director; therefore, I am requesting that you approve this request for the purchase of light refreshments.

If you have any questions or need additional information, please contact me at 202.564.2192.

Approved:



Date: 10/31/19

Christopher S. Robbins
Deputy Assistant Administrator for Management
Office of Research and Development

